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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/080,787

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Robert A. Rabiner

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,787

Applicant(s)

RABINER ET AL.

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/30/2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims that the anchoring mechanism is "wing-like." Although, this terminology has antecedent basis in the specification, it is unclear what this phrase means. "Wing-like" in what aspect? Does Applicant mean that the anchoring mechanism has a free distal end like a wing? Does Applicant mean that the anchoring mechanism is shaped triangularly like a common wing on an airplane? Or does Applicant mean that the anchor is flat like a wing? There are many different shapes of wings. It is unclear what Applicant is trying to claim by describing the anchors as "wing-like."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Publication No. US 2002/0007130 to Burbank et al. Regarding Claims 1, 3, 10-12, Burbank discloses a catheter/anchoring mechanism, according to Applicant's invention. Burbank discloses an elongated, hollow shaft, which contains an anchoring mechanism. Actuating mechanism (98) pushes the anchor from a retracted position to an extended position (para. [0062]). The anchoring mechanism (94d) of Fig. 17 is wing like in that it is triangular in shape, flat, and protrudes from both sides of the catheter. Anchoring mechanism (102) of Fig. 18 is wing like in that it has one end attached to the central axis and a free lateral end. The embodiment of Fig. 19 shows anchoring member (106) protruding exactly how Applicant's anchor protrudes. Each of these embodiments have retracted positions and extended positions, in which the anchoring members (wing-like members) are *extended outside of a cannula* and atraumatically hooked onto the inner surface of a body lumen. Each of these embodiments is used to secure the distal end of the catheter to the body (paragraph [0060]). Each of the aforementioned embodiments are alternatives to bonding agents (glues) (paragraph [0062] and additionally [0063-0066]).
3. Regarding Claim 2, Burbank discloses anchoring his device to "a lesion" inside of the body (paragraph [0011]). It is certainly capable of being anchored to an aorta, a vessel (such as the stomach), an access port, or a graft.
4. Regarding Claims 4 and 9, Burbank discloses a rotating mechanism that allows the vascular introducer to change direction within the blood vessel without being removed. By way of illustration, if one inserted the end of a pencil into a hole formed

in a blood vessel, one *would be able to rotate it. There would be nothing preventing one from doing so.* The mechanism would merely be the end of the shaft, lubricated by the blood of the vessel. The absence of a protrusion, roughened section, or interfering component will allow the introducer to be rotated.

Applicant does not claim any particular structure that does this, nor does he show in the pictures what such a mechanism should look like. Applicant discloses in the specification that the mechanism can be a ball-and-socket arrangement, a hinged arrangement, etc, but it is unclear how these mechanisms would function at the end of the device. Regardless, Applicant has not set forth any of these specific mechanisms *within the claims.*

5. Regarding Claims 5-7 and 13-15, since the instrument is meant to perform a biopsy (take tissue from the body and pull it through tube (58)) it certainly has space for having an ultrasonic probe for ablating tissue inserted through it as well. In fact an ablater (86) capable of being operated ultrasonically instead of using RF energy [0057].
6. Regarding Claims 8 and 16, the device is capable of being used once on a single patient and then discarded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 17-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,707,359 to Bufalini in view of U.S. Patent No. 5,971,983 to Lesh.
- Regarding Claims 17, 20, 25, and 31, Bufalini discloses a vascular introducer/shaft (32) with anchoring mechanisms (46) into a vascular access device (56). The vascular introducer is hollow to accommodate the removal of various internal organs therethrough [Column 1, lines 25-36]. *Each anchoring mechanism (46) is a separate, flat "rib" [Column 3, lines 56-64] and resembles a wing in that each is flat, long, and has one free distal end.* Bufalini illustrates engaging an anchoring mechanism (36) to the inner surface of the vascular access device at a puncture site in Figure 8. Such an anchoring system would be atraumatic. Bufalini does not disclose inserting an ultrasonic probe through his trocar.

However, Lesh discloses a trocar and anchoring assembly and teaches inserting an ultrasonic probe [Column 15, lines 20-60] through his assembly and into a vascular access device (such as the heart or other body organs). He does so in order to ablate debris [Column 9, lines 55-61]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use an ultrasonic probe in conjunction with the trocar of Bufalini (vascular introducer) in order to ablate tissue, as taught by Lesh.

8. Regarding Claim 18, the vascular access device is a vessel (the abdominal cavity) [Column 1, lines 34-37; Column 4, lines 19-25].

9. Regarding Claims 19 and 27, the debris is a lesion, which is a diseased portion of a tissue that can often cause blockages [Column 4, lines 52-58].
10. Regarding Claims 21 and 26, Lesh discloses a stylet (5) ablation wire similar to Applicant's component (30) that extends through the lumen of his device and out the distal end [Column 15, lines 36-40]. Lesh teaches that the user should "sweep" the ablation element "like a compass" [Column 15, lines 56-60] in order to ablate various parts of the tissue.
11. Regarding Claims 22 and 28, the anchor will maintain contact with the abdominal wall, as the specimens are extracted through the vascular introducer (32) because of the force. Figure 8 shows the anchor (36) in contact with the wall, and the anchor is too big to fit through the hole in the vascular access device (56).
12. Regarding Claims 23, 24, 29, and 30 the anchor is retractable and extendable when activation mechanism (50) moves, as shown in the progression from Fig. 7 to Fig. 8.
13. Claims 17-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Publication No. US 2002/0007130 to Burbank et al. in view of U.S. Patent No. 5,971,983 to Lesh. Burbank discloses all of the mechanical features set forth in independent claims 17 and 26 and each dependent claim, as explained above. "Radially extendable and retractable" ablation device/probe (86) passes through the vascular introducer (through the slot in the distal end of the tubular vascular introducer) and into the vascular introducer in order to ablate debris therein {paragraph [0057]}. However, the probe (86) is energized with RF energy rather

than ultrasonic energy. Lesh teaches the equivalency of RF energy and ultrasonic energy to ablate tissue. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to employ ultrasonic energy rather than RF energy to ablate tissue, as they are alternate and equivalent ways of vibrating a probe to ablate tissue, as taught by Lesh.

14. Regarding Claims 21 and 26, Lesh discloses a stylet (5) ablation wire similar to Applicant's component (30) that extends through the lumen of his device and out the distal end [Column 15, lines 36-40]. Lesh teaches that the user should "sweep" the ablation element "like a compass" [Column 15, lines 56-60] in order to ablate various parts of the tissue.
15. Regarding Claims 22 and 28, the anchor will maintain contact with the internal organ, as the specimens are extracted through the vascular introducer (32) because of the force of the anchoring mechanisms on the interior of the body (paragraph [0062]).
16. Regarding Claims 23, 24, 29, and 30 the various embodiments of the anchor are retractable and extendable when activation mechanism (98) moves, as shown in Figures 14-21.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,512,037 to Russell et al.

U.S. Patent No. 5,351,679 to Mayzels et al.

U.S. Patent No. 4,909,789 to Taguchi et al.

Art Unit: 3731

U.S. Patent No. 4,830,002 to Semm, Kurt

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 8, 2004


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

9/15/04